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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/442,284	11/19/1999	RAPHAEL F. MELOUL	MENLO-103-DI	5637

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GARY W MCFARRON
STEPHEN B HELLER
COOK MCFARRON & MANZO LTD
Ste 2850 200 West Adams
CHICAGO, IL 60606

EXAMINER	
GHAFOORIAN, ROZ	
ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 06/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/442,284	Applicant(s) MELOUL ET AL.	
	Examiner Roz Ghafoorian	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-22 and 38-40* is/are pending in the application.

4a) Of the above claim(s) *1-18,23-37 and 41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-22 and 38-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims19-20, 22 and 39-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 39 states "lining comprises a high density/low density polyethylene", it is unclear what the definition of High/Low density is, therefore the examiner has interpreted the claim as the lining comprises a high density OR low density polyethylene.

b. Claim 19 recites the limitation "central opening" in line 12. There is insufficient antecedent basis for this limitation in the claim.

c. Claim 22 recites the limitation "a patient" in line 4. There is insufficient antecedent basis for this limitation in the claim.

d. Claim 40 recites the limitation "the proximal end" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

1. Claim 19 is rejected under 35 U.S.C. 102(e) as being clearly anticipated by U.S Patent No.5899882 to Waksman et al. Waksman discloses an apparatus and method for delivery of a treating element, such as a radiation source, through a catheter to a desired site in the intraluminal passageways of a patient. The catheter is sized for insertion of the distal end portion through the vascular system of a patient to a selected area to be treated. After the treating element is loaded into the lumen pressurized blood-compatible liquid, such as sterile saline solution or sterile water, is introduced via liquid source through a port in the proximal end of the lumen behind the treating element. The liquid, which provides the motive force for moving the treating element, may be allowed to exit from the distal end of the catheter. (Col.6, lines 60-65) Waksman also discloses a three-lumen catheter system with a transfer device containing treating

elements and connected to the proximal end of a three lumen catheter tube.(Col.8, lines 6-10) The third port opens into the third bore of the body and is adapted to receive a guide wire to aid in positioning the distal end of the catheter tube within a patient (col.8, lines 25-30).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claim 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S Patent No.5451233 to Yock, and further in view of U.S Patent No. 4838881 to Bennett et al

Yock discloses an angioplasty apparatus facilitating rapid exchanges. This apparatus comprises of an elongated tube having a proximal end and a distal end, firs and second lumens extending between the proximal and distal ends and communicating. The first lumen receives the treating element, as well as containing a radiopaque marker located within its distal end. (Col.7, lines 43-45) This elongated tubular membe5 with tow inner lumens extending therein, one of the two inner lumens being in fluid communication with the second inner lumen in the distal shaft. (Col 14, lines 20-29)

Yock, however, does not teach the lumens of the catheter having an elliptical cross section. Bennett discloses a multilumen catheter comprises separate proximal IV

tubes of substantially circular cross-section welded in fluid communication with each of the substantially elliptical-shaped lumens of the catheter.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to have combined the two studies. Because as states by Bennett, elliptically shaped lumens essentially eliminate flow problems caused by lumen wall junctures while at the same time using available catheter cross-section area more efficiently than circular-shaped lumens. Whereas a case can be made that elliptically shaped lumens are optimal for the design of a multilumen catheter. (Col.2, lines 26-30)

3. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Waksman and further in view of Bressler et al U.S Patent No. 5466223.

Waksman disclose an apparatus and method for delivery of a treating element, such as a radiation source, through a catheter to a desired site in the intraluminal passageways of a patient, with a the proximal end having a keyed fitting (a detent) to allow attachment of only certain catheters to the fitting on the loading device. (Col. 13, lines40-45) Waksman, however, does not contain a cantilever arm axially. Bressler discloses a needle assembly, which includes both a detent and a cantilever arm.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to have combined the studies, because according to Bressler cantilever allows for a snapping motion which provides an audible indication to the user that the locking had taken place. (Col.9, lines 45-50)

4. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Waksman, and further in view U.S Patent No.5960796 to Sung et al or U.S Patent No.5706809 to Littmann et al. .

As discussed above Waksman disclose an apparatus and method for delivery of a treating element, such as a radiation source, with mulitluminal catheter. Waksman does not teach a lining in the lumen, nor does Waksman teach the use of high density/low density polyethylene on the lining of the lumen. However the idea of utilizing lining made from polyethylene is not a unique and new idea to the art. Littmann and Sung are just two examples in which polyethylene lining has been used.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to have combined the studies, because according to both Littmann and Sung the lining increases the lubrication of the lumen. (Col 6, lines 25-30 in Sung)

5. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Waksman, and further in view of U.S Patent No.4364376 to Bigham or U.S Patent No.6047381 to Dinh et al or U.S Patent No.6251059 to Apple et al.

As discussed above Waksman disclose an apparatus and method for delivery of a treating element, such as a radiation source. Waksman protects its user against radiation by utilizing a carriage, which the radiation source is loaded in to. The carriage is preferably made of a material and has sufficient thickness to protect the user against

unnecessary exposure to radiation when the treating elements are radioactive. (Col.8, lines 46-50) Waksman however does not disclose a shield on the tube. The idea of some type of protection against radioactive exposure is not new in the art. Ever-since it has been scientifically proven that radioactive exposure will lead to development of different types of carcinoma and infertility, there has been an increase level of caution when handling radioactive material. Bigham, Dinh, and Apple are just a few examples of the radioactive shields that have been used to block the exposure to of radiation rays.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to have combined the studies, because it would be obvious to a have some type of shield on the catheter for protection against the potential exposure of radiation.

Response to Arguments

6. Applicant's arguments filed 5-14-02 have been fully considered but they are not persuasive.

a. The applicant arguers that in claim 19 Waksman et al does not meet the claim limitation and refers to a passage in the Specification. The applicant is correct in pointing out that Waksman reference does not meet with the expanded explanation in the Specification, however, that explanation is not projected in the claims. The limitations in claim 19 read on a catheter with at least one detent on the proximal end the rest of the claim defines functionality and Waksman's apparatus is capable of performing the functions recited in claim 19. Therefore,

in *re of Johnson & Johnston Ass. Vs. R.E. Service Co., INC 285 F.3d 1046* Waksman does meet all the limitations recited in claim 19.

b. Claim 20, the applicant argues that Waksman does not contain a detent; furthermore applicant does not understand the motivation in combining the Waksman and Bressler. As pointed out in the office action above Waksman contains a catheter with a the proximal end having a keyed fitting (a detent) to allow attachment of only certain catheters to the fitting on the loading device. (Col. 13, lines 40-45). According to Bressler adding a cantilever arm to the keyed fitting (detent) structure allows for a snapping motion, which provides an audible indication to the user that the locking had taken place. (Col.9, lines 45-50) The applicant states this motivation is "a stained use of hindsight", Bressler teaching disagrees with the applicant argument because according to Bressler it is important for the care giver to know when the device has been locked in, in order to avoid any potential complications. If the care giver has not properly assembled the device there is a huge risk of the apparatus to unravel in the middle of a procedure which would ultimately lead to multiple complications.

c. Claims 21-22, the applicant argues that Bennett teaches away form the use of ellipse shaped catheter. But the applicant has misread the reference, Bennett states "a device of unitary contraction comprising a multilumen venous catheter having *elliptically* shape lumen. Integrally attached to each lumen of the catheter is a proximal IV tube having a *generally circular cross*-section." (Col. 3, lines 34-37) Bennett clearly teaches an elliptically shaped lumen catheter, and

has pointed out several advantages of the elliptical shaped of the lumen. Bennett further teaches an IV tube with a generally circular cross-section. Bennett's entire patent discloses why it is beneficial to use a catheter with elliptical shaped lumen and the IV tube has a *General* Circular cross-section. A general circular cross-section is NOT completely circular. Therefore it is confusing how the applicant could have categorized Bennett as a reference that teaches away form an elliptical shaped lumen.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roz Ghafoorian whose telephone number is 703-305-2336. The examiner can normally be reached on 8:30am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. .

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

RG
May 24, 2002

ANHTUAN T. NGUYEN
PRIMARY EXAMINER
A/SPE 6/3/02